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09/737,004	12/14/2000	Suzanne F. Groemminger	P02977	8548

7590

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EXAMINER

DELCOTTO, GREGORY R

ART UNIT

PAPER NUMBER

1751

DATE MAILED: 10/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/737,004

Applicant(s)

GROEMMINGER, SUZANNE F.

Examiner

Gregory R. Del Cotto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 1-20 are pending.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a composition for cleaning and wetting a contact lens, classified in class 510, subclass 11<sup>2</sup>~~7~~.
- II. Claims 13-20, drawn to a method of cleaning and wetting a contact lens, classified in class 134, subclass 901.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the composition of Group I can be used in a materially different method such as in a method of cleaning hard surfaces.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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During a telephone conversation with John Thomas on August 20, 2002, a provisional election was made with traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to components (a) and (c), these components present the problem of double inclusion in that these components overlap in scope and may represent the same compound or component. Note that, each component must represent a separate entity. Claims in which one component is defined so broadly that it reads on a second, fail to meet the requirements of the second paragraph of 35 USC 112. See Ex parte Ferm et al, 162 USPQ 504.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/37049.

'049 teaches an ophthalmic solution for the treatment of contact lenses while worn in the eye containing an ethoxylated glucose derivative, tyloxapol, and a polyoxyethylene-polyoxypropylene nonionic surfactant. See Abstract. The ethoxylated glucose derivative functions as the wetting agent. See page 5, lines 20-30. The nonionic polyoxyethylene-polyoxypropylene surfactants have an HLB of at least 18. such surfactants can be selected from the group of commercially available surfactants having the name poloxamine or poloxamer. Poloxamine surfactants consist of a poly(oxypropylene)-poly(oxyethylene)adduct of ethylene diamine having a molecular weight from about 7,500 to about 27,000 wherein at least 40 weight percent of said adduct is poly(oxyethylene). These are sold under the tradename Tetronic. An analogous series of surfactants is the poloxamer series which is a polyoxyethylene, polyoxypropylene block polymer under the trademark Pluronic. See page 6, lines 1-20.

Optionally, additional compatible surfactants that are known to be useful in contact lens wetting or rewetting solutions can be used in the solutions. Suitable nonionic surfactants include polyethylene glycol esters of fatty acids such as polysorbate 20, polyoxyethylene (23) lauryl ether, etc. See page 7, lines 10-20. Additionally the composition may include nonionic polymeric demulcent and viscosity builder. Suitable viscosity builders include hydroxyethyl methylcellulose, etc. See page 7, lines 30-45. The compositions will also contain a disinfecting amount of a preservative or antimicrobial agent such as the hydrochloride salt of polyhexamethylene biguanide, etc. See page 8, lines 15-40. The pH of the composition should be maintained within the range of 5.0 to 8.0 and suitable buffers include boric acid, sodium borate, etc. See page 9, lines 20-30.

'049 does not specifically teach a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '049 suggest a cleaning solution containing a non-amine

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polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

Claims 1-4 and 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/43373.

'373 teaches compositions and methods used in the eye and/or out of the eye

inhibitors of proteinaceous deposits on hydrophilic contact lenses. See Abstract. A

disinfecting amount of antimicrobial agent may be used such as hexamethylene

biguanides and their polymers and water-soluble salts. See page 9, lines 10-25.

Neutral or nonionic surfactants may impart cleaning and conditioning properties and are

usually present in amounts up to 15 weight percent. The surfactants usually have a

hydrophilic-lipophile balance (HLB) of 12.4 to 18.8. Satisfactory nonionic surfactants

include polyethylene glycol esters of fatty acids such as polysorbate 20,

polyoxyethylene (23) lauryl ether, etc. Other nonionic surfactants include

poly(oxypropylene)-poly(oxyethylene) adduct of ethylene diamine having a molecular

weight from about 7,500 to about 27,000. It may also be desirable to include water-

soluble viscosity builders such as hydroxyethyl or hydroxypropyl cellulose, etc.

Additionally, active ingredients such as tonicity agents, buffers, and sequestering agents

may be added. In order to maintain the pH of the cleaning and conditioning solutions

within the range of 3 to 9, suitable buffers may be added such as boric acid, sodium

borate, etc. See page 11, lines 20-35.

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'373 does not specifically teach a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims, with a reasonable expectation of success and similar results with respect to other disclosed components, because the broad teachings of '373 suggest a cleaning solution containing a non-amine polyethyleneoxy-containing material, a first nonionic surfactant, a second nonionic surfactant, a wetting agent, and the other requisite components of the composition in the specific proportions as recited by the instant claims.

### ***Conclusion***

2. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (703) 308-2519. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yogendra Gupta can be reached on (703) 308-4708. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-3599 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

GRD  
October 17, 2002

GREGORY DELCOTTO  
PRIMARY EXAMINER

